



<b>Title</b>	<b>Development and Validation of Methods for Assessing the Quality of Diagnostic Accuracy Studies</b>
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<b>Reference</b>	Health Technol Assess 2004;8(25). June 2004. <a href="http://www.nchta.org/execsumm/summ825.htm">www.nchta.org/execsumm/summ825.htm</a>

## Aim

To develop a quality assessment tool for use in systematic reviews to assess the quality of primary studies of diagnostic accuracy.

## Conclusions and results

The reviews identified 28 items for possible inclusion in the quality assessment tool. In the first review, the sources of bias supported by the most empirical evidence were: variation by clinical and demographic subgroups, disease prevalence/severity, partial verification bias, clinical review bias, and observer/instrument variation. There was also some evidence of bias for: effects of distorted selection of participants, absent or inappropriate reference standard, differential verification bias, and review bias. Evidence for other sources of bias was insufficient to draw conclusions regarding potential effects of these biases.

The second review found that the quality assessment tool should have the potential to be: discussed narratively, reported in a tabular summary, used in recommendations for future research, used to conduct sensitivity or regression analyses, and used as criteria for inclusion in the review or a primary analysis. A distinction should be made between high- and low-quality studies. Component analysis was identified as the best approach to incorporate quality into systematic review of diagnostic studies, and this was considered in developing the quality tool.

The third review found that only 1 item (avoidance of review bias) appeared in more than 75% of the tools, while 4 additional items (spectrum composition, population recruitment, absent or inappropriate reference standards, and verification bias) appeared in 50% to 75% of the tools. Further items appeared in fewer than 50% of the tools.

## Methods

Three systematic reviews were conducted to provide an evidence base for developing the quality assessment tool:

- review of the methodological literature on diagnostic test assessment to identify potential sources of bias
- systematic reviews of diagnostic tests that utilized any form of quality assessment to identify how quality was incorporated
- review of quality assessment tools to ascertain existing methods for assessing the quality of diagnostic studies and the evidence on which they are based.

A Delphi procedure was used to develop the quality assessment tool. This process incorporated the information yielded by the reviews. The Delphi procedure resulted in a quality assessment tool known as "QUADAS", the acronym for Quality Assessment of Diagnostic Accuracy Studies. (Please see the full monograph for further details.) A background document describes each item included in the tool and how it should be scored.

## Further research/reviews required

Further work to validate the tool continues beyond the scope of this project. Further development of the tool by adding design- and topic-specific criteria has been proposed.